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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/617,565

07/11/2003

Li Nie

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30955

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EXAMINER

WEIER, ANTHONY J

ART UNIT

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1794

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/617,565	<b>Applicant(s)</b> NIE ET AL.	
	<b>Examiner</b> Anthony Weier	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 17-23, 26 and 45-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16, 24, 25, 27-44 and 50-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/20/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-5, 7-16, 24, 25, 27-33, 41, 42, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/13521 (Wang et al) with evidence from Kitabatake et al.

Wang et al discloses a resin formation formed into a pet chew treat wherein said resin formulation may contain animal protein (e.g. egg white) and plant protein (e.g. wheat, corn) wherein same may be used alone or in combination and wherein said protein may be either native or hydrolyzed, said formulation being palletized (page 8). Example 7 discloses the use of approximately 50% soy protein isolate (e.g. the grain protein called for in the instant claims) and approximately 10% animal protein or protein derivative of same. Although it is not specified in this example that the animal-derived protein is hydrolyzed, it would have been obvious to one having ordinary skill in the art to have hydrolyzed same (with or without the grain protein) to contribute to or provide better processing flowability (see page 3). As for the particular molecular weight of said protein (instant claims 24 and 25), absent a showing of unexpected results, it would have been further obvious to have arrived at same as a matter of preference depending on the particular protein moiety available or the cost of same.

Wang et al also discloses the presence of a plasticizer (e.g. glycerol) in an amount of as high as 30%, water as low as 10% (see claim 1), and vegetable powders (as the additional ingredient of claim 41) in an amount of, for example, 2% in Example 7.

The claims further call for the grain protein in the pellets to be substantially undenatured. Although Wang does provide in the examples a temperature strategy for extruding the pellets, there is no restriction on the temperature to be used other than providing a product having good flow when used in preparing the injected molded article. It should be further noted that with respect to the temperatures strategy employed, for example, in Example 1, would not result in a grain protein that is denatured if the moisture content is low enough. Wang et al further discloses using a moisture content of as low as 10% (see Claim 1), and it would have been further obvious to one having ordinary skill in the art at the time of the invention to have employed same as a matter of preference within the compositional scope claimed therein. Use of such low moisture would require much higher temperatures than called for in the instant claims to achieve fully denatured soy protein as evidenced in the study of Kitabatake et al (e.g. inset graph of Figure 6) . Moreover, even if the moisture content is higher, it is expected that the speed of treatment in during extrusion would not allow for significant denaturation to occur, thus providing a product that is substantially undenatured.

3. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al and Axelrod et al (U.S. Patent No. 6159516).

The claims further call for the presence of the protein originating from chicken liver. Such are well known as taught, for example, by Axelrod et al that teaches a molded chewable pet food which contains a liver protein material (col. 8, lines 55-62). It would have been obvious to one having ordinary skill in the art at the time of the invention to have included liver protein in the product of Wang et al as a matter of preference depending on what protein is available, the cost of same, and the nutritional needs of the pet and to have further hydrolyzed same as discussed in the rejection above.

4. Claim 34, 35, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al and Pater et al.

The claims further call for the presence of a lubricator in amounts and type as called for in the instant claims. Pater et al discloses a molded chewable pet food containing lubricants such as fatty acid derivatives and in amounts as high as 5%. It would have been obvious to one having ordinary skill in the art at the time of the invention to have included same for the art recognized flow enhancing effect attributed to same.

The claims also call for the presence of a mold release agent. Pater et al further teaches incorporating same (calcium stearate; see claim 12). It would have been further obvious to have included same for such art recognized use. As for the amount of same employed, such would have been well within the purview of a skilled artisan, and it would have been further obvious to have arrived at same through routine experimental optimization.

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5. Claims 34-36, 38-44 and 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al and Jane et al.

The claims further call for the presence and amount of a particular reducing agent. Jane et al teaches an edible molded article (which may be used for pets; col. 7, lines 49-60) prepared from a soybean material wherein a reducing agent such as sodium pyrosulfite (i.e. sodium metabisulfite) is incorporated to aid in the dispersibility of the protein component in preparing the material to be molded (e.g. col. 1, lines 23-37; claim 10). It would have been obvious to one having ordinary skill in the art at the time of the invention to have employed same in the Wang et al product for such reason.

The claims also call for the presence of modified starch of a particular type and amount. Jane et al further teaches the use of a chemical modified starch and a starch sourced from, for example, wheat or corn (e.g. col. 3, lines 54-67) wherein same is used in conjunction with soybean protein material. It would have been obvious to one having ordinary skill in the art at the time of the invention to have incorporated such starch as a filler to provide "better flowability, better water resistance, and to decrease the cost of same" (col. 3, line 47-53). As for the amount of same to be used, Jane et al teaches the preparation employing 20-30% of same. It would have been further obvious to have employed such amount in Wang et al for such benefit.

The claims further call for a mold release agent and amount of same. Jane et al teaches such an agent (e.g. lubricant; col. 4, lines 31-36), and it would have been further obvious to have incorporated same for such reason. It would have been well within the purview of a skilled artisan to determine the particular amount of agent to be

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used, and it would have been further obvious to have arrived at such amount as a result effective variable.

The claims call for the presence of a lubricant such as fatty acid. Jane et al further teaches the use of same (col. 4, lines 31-36), and it would have been further obvious to have employed same for the reasons above: to facilitate the removal of the product from its molding device. It would have been well within the purview of a skilled artisan to determine the particular amount of agent to be used, and it would have been further obvious to have arrived at such amount as a result effective variable.

### ***Response to Arguments***

6. Applicant's arguments filed 9/24/08 have been fully considered but they are not persuasive.

Applicant argues that the use of added plasticizer in conjunction with water in the Wang et al molding mixture would result in denaturation of same as suggested by evidence from De Graaf which appears to teach that increasing the plasticizer content (water and otherwise) in such a protein material will lower the threshold for protein denaturation. Moreover, Applicant argues that when Wang et al employs a water content of 10% a significant amount of plasticizer is employed to facilitate good flow conditions. It should be noted, however, that although less desirable Wang et al does disclose preparing a molded article in the unpreferred "region C" comprising a mixture having water content of 10% with very little to no plasticizer. In view of the evidence of Kitabatake et al as recited in the rejections above, heat denaturation would not occur in such case. Moreover, Wang et al calls for the presence of as low as 10% water with

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0% added plasticizer. Taking these endpoints together, Wang et al would produce a mixture not having a preferred flow as shown in Fig. 2 (Region C). Even so, Wang et al includes same within the scope of claimed invention therein and provides no suggestion of teaching away from same. In addition, it should be noted that Wang et al discloses other examples of similar mixtures such as in Example 2, Sample 1 wherein the composition is essentially soy protein isolate, about 11% water, and a tiny amount of added plasticizer exposed to extruder temperatures only as high as 110 C. Examining again the inserted graph of Fig. 6 in Kitabatake et al, it is clear that the denaturation temperature is not even close to being reached following this example in Wang et al. it should be further noted that De Graaf does not appear to take into consideration differences attributed to water as opposed to added plasticizer like glycerol. Instead, De Graaf looks at the presence of plasticizer in general (whether it be water or combinations of water and glycerol) and teaches that the addition of plasticizer in general decreases the temperature threshold for glass transition and denaturation. Even if one were to include the miniscule amount of added glycerol in Wang et al, the amount of plasticizer (water and added glycerol) required to enter a region of denaturation for sample 1 of Example 2 is never close to being attained.

All other arguments have been addressed in view of the rejections above.

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony Weier whose telephone number is 571-272-1409. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Anthony Weier  
January 5, 2009